REMARKS

Claims 1-5, 7-9, 11-13, 37 and 38 are pending in this application. Applicants respectfully request reconsideration of the claims of this application in view of the following comments.

Compliance of Claims 1-5, 7, 8, 13 and 37 with 35 U.S.C. §103(a)

The Office Action rejects claims 1-5, 7, 8, 13 and 37 under 35 U.S.C. §103(a) as unpatentable over Ding et al. (U.S. Patent No. 5,899,935) and Choi et al.(*Biomaterials* (2000) **21**:469-473). Applicants respectfully traverse this rejection and request the Examiner to reconsider in view of the following comments.

(a) Modifying Ding et al. in the Manner Suggested Would Alter Its Principle of Operation

To Applicants' understanding Ding et al. disclose coating systems that cover a stent to prevent its self-expansion during implantation. As explained in Ding et al. at column 3, lines 22-36, a conventional self-expanding braided stent may be implanted by radially compressing it and using a delivery catheter to deliver the stent proximate the site of a lesion to be bridged. An outer sleeve is withdrawn to expel the compressed stent from the distal end of the delivery catheter, thus permitting the stent to self-expand, radially, so that it will continue to press itself against the interior wall of the blood vessel.

Ding et al. provide "a method of making an otherwise self-expanding stent balloon expandable" (Ding et al. at column 1, lines 8-9). According to this method, a braided stent is "frozen" in its elongated, reduced diameter configuration with a polymeric or inorganic coating (Ding et al. at column 3, lines 40-62). To deploy the stent, the stent "may be placed over an uninflated balloon on a balloon-type stent delivery catheter" (Ding et al. at column 4, lines 22-24). "[A]s inflation of the balloon takes place and the stent begins to expand, the brittle coating bonding the stent strand intersections are broken and the stent is allowed to self-expand to the point where it presses against the vessel wall with a force sufficient to maintain the stent in place following deflation of the delivery balloon and removal of the catheter" (Ding et al. at column 4, lines 27-33). Alternatively, "even without balloon expansion, the treated stent will recover by itself as the polymer matrix loses structural integrity due to the dissolving powders" (Ding et al. at column 4, lines 50-52).

Thus, Applicants submit that Ding et al. teach that the fracture or degradation of the described

coating is a necessary event to permit radial expansion of the stent, and must take place in order to practice the invention disclosed by Ding et al. At column 3, lines 61-62, Ding et al. note that ceramic coatings are "quite brittle". Applicants submit that Ding et al. do not disclose or suggest a coating for a stent that does not break when the stent is deformed. Furthermore, modification of Ding et al. to provide a coating that does not break when the stent is deformed would render the device taught by Ding et al., i.e. a balloon expandable self-expanding stent, unsatisfactory for its intended purpose, as the stent would be incapable of self-expansion if the coating failed to break or degrade and instead restrained the stent in its radially compressed, stretched condition.

Applicants submit that in order for a *prima facie* case of obviousness to be made out, the proposed modification cannot render the prior art unsatisfactory for its intended purpose: MPEP §2143.01(V). In the present case, it is submitted that it is the breaking of the bonds in the coatings taught by Ding et al. which provides the desired function. Modifying Ding et al. with a ceramic coating configured such that the coating would not break or otherwise degrade when the stent is deformed for implantation would thus render the invention taught by Ding et al. unsatisfactory for its intended purpose, specifically "providing a balloon expandable braided stent with a restraint to initially prevent self-expansion" (Ding et al. at Abstract) [emphasis added]. Accordingly, it is submitted that Ding et al. cannot be applied to raise a case of *prima facie* obviousness against the claims of the present application.

With respect to Choi et al., to Applicants' understanding, Choi et al. teach deposition of hydroxyapatite on metals such as titanium. However, Applicants emphasize that substrates such as those disclosed by Choi et al. do not undergo deformation after deposition of the coatings. Accordingly, Applicants submit Choi et al. do not disclose deposition of hydroxyapatite on deformable substrates, and therefore do not remedy the deficiencies noted above in the teachings of Ding et al. Accordingly a *prima facie* case of obviousness has not been established based on the combination of Ding et al. and Choi et al.

(b) The Cited References Teach Away From Their Combination

Furthermore, it is submitted that Ding et al. and Choi et al. teach away from providing a ceramic coating on a deformable implantable device such as a stent. Ding et al. specifically teach that ceramic coatings are "quite brittle" (Ding et al. at column 3, lines 61-62). As noted

by the Examiner, Choi et al. teach at the second paragraph of the Introduction on page 469 that if a coating layer is separated from an implant during applications in the human body, the detached fragments "have very adverse effects on the implant or the tissue surrounding it". Choi et al. do not disclose deposition of hydroxyapatite on deformable substrates. Accordingly, one skilled in the art seeking to provide a coating for a deformable implantable medical device that does not fracture during deformation would not seek to use a ceramic, taught as brittle by Ding et al., in view of the teachings of Choi et al. to the effect that detached fragments of a coating layer may have adverse effects. For this reason as well, Applicants submit that the combination of Choi et al. and Ding et al. is improper and does not establish a *prima facie* case of obviousness.

The Examiner is, therefore, respectfully requested to reconsider and withdraw the rejection of claims 1-5, 7, 8, 18 and 37 based on the combination of Ding et al. and Choi et al.

Compliance of Claims 9 and 11 with 35 U.S.C. §103(a)

The Office Action rejects claims 9 and 11 under 35 U.S.C. §103(a) as unpatentable over Ding et al. and Choi et al., further in view of Mancini et al. (*J. Materials Sci.* (2001) **36**: 3891-3896) and Mitoh et al. (U.S. Patent No. 5,851,670).

For the reasons set forth above, Applicants submit that the combination of Ding et al. and Choi et al. cannot be applied to raise a case of *prima facie* obviousness with respect to the claims of the present application.

In respect of Mancini et al., to Applicants' understanding this paper describes thick hydroxyapatite films produced by thermal spraying. Applicants submit that this methodology is not applicable to coating stents, as the method produces films which are too thick and have unacceptably poor microstructure. While the relationship between porosity and crystallinity for hydroxyapatite films may be relevant to thermal spraying of other types of implants (for example, dental or hip implants that do not undergo deformation after coating), Applicants submit that the relationships discussed in Mancini et al. are not applicable to thin submicron hydroxyapatite films on stents. To Applicants' understanding, Mancini et al. do not make reference to stents or coating of stents with hydroxyapatite. Accordingly, Mancini et al. do not

remedy the shortcomings noted above with respect to the combination of Ding et al. and Choi et al.

With respect to Mitoh et al. (U.S. Patent No. 5,851,670), Applicants submit that this reference describes *in vivo* soluble composite particles including a calcium phosphate coating for eluting a drug. Applicants submit that drug elution from a coating on a stent is a very different process from drug elution from a particle. For example, the effective surface area of a particle, per unit weight, may be 100 to 1000 times larger than that of a coating on a stent. To Applicants' understanding, Mitoh et al. do not make reference to stents. Accordingly, Mitoh et al. does not remedy the shortcomings noted above with respect to the combination of Ding et al., Choi et al. and Mancini et al.

As the references applied in the Office Action are submitted not to raise a *prima facie* case of obviousness with respect to claims 9 and 11, the Examiner is respectfully requested to reconsider and withdraw the rejection of claims 9 and 11 on the basis of the combination of Ding et al., Choi et al., Mancini et al. and Mitoh et al.

Compliance of Claim 11 with 35 U.S.C. §103(a)

The Office Action further rejects claim 11 as unpatentable over Ding et al., Choi et al., Mancini et al., and Mitoh et al., further in view of Falotico et al. (U.S. patent application publication No. 2001/0029351).

For the reasons stated above, Applicants submit that the combination of Ding et al., Choi et al., Mancini et al. and Mitoh et al. does not raise a *prima facie* case of obviousness with respect to claim 11. Further, as explained in the response to the previous Office Action filed 18 December 2008, Applicants submit that Falotico et al. describe standard methods for coating a stent, i.e. either the use of discrete pockets or reservoirs within the metal stent itself, or a polymer coating, which is a deformable material that can withstand the deformation of a stent. There is no mention in Falotico et al. of the use of a rigid material such as a ceramic, e.g. a calcium phosphate, for coating a stent. Thus, Applicants submit that the coatings shown in Falotico et al. are inapplicable to the coating of stents with a ceramic. Based on the state of the art as represented by Falotico et al., particularly when viewed in light of the teachings of Ding et al. as to the brittleness of ceramic and of Choi et al. as to adverse effects that detached

fragments of a coating layer may have when deployed *in vivo*, one skilled in the art would have believed that a calcium phosphate would be too rigid and/or brittle for coating a deformable structure such as a stent.

Accordingly, the Examiner is respectfully requested to reconsider and withdraw the rejection of claim 11 on the basis of the combination of Ding et al., Choi et al., Mancini et al. and Mitoh et al. further in view of Falotico et al.

Compliance of Claim 12 with 35 U.S.C. §103(a)

The Office Action further rejects claim 12 as unpatentable over Ding et al., Choi et al., Mancini et al., Mitoh et al., and Falotico et al. further in view of Pacetti (U.S. Patent No. 6,663,664).

As explained above with respect to claim 9, Applicants respectfully submit that the combination of Ding et al., Choi et al., Mancini et al. and Mitoh et al. does not raise a *prima facie* case of obviousness with respect to claim 9. The Office Action further applies Falotico et al. and Pacetti in respect of claim 12 to show that the drug inhibits restenosis. Applicants respectfully submit that the further addition of Falotico et al. and Pacetti does not raise a case of *prima facie* obviousness with respect to claim 12.

As outlined in the response to the previous Office Action filed 18 December 2008, and as explained above, Applicants submit that Falotico et al. is directed to a polymeric coating, which is known to be deformable and thus capable of coating a deformable device, and the teachings of Falotico et al. are therefore inapplicable to a calcium phosphate coating. Pacetti is likewise submitted to be inapplicable to claim 12, as Pacetti fails to disclose a calcium phosphate coating having a thickness of no more than 1 μm as claimed. As outlined in the response to the previous Office Action filed 18 December 2008, Pacetti requires that the biodegradable member control the radial force of a stent and withstand the stress of maintaining the stent in a collapsed position prior to expansion. If one were to choose calcium phosphate as the biodegradable member, they would not have selected a thickness of less than 1 μm to control radial expansion forces. Accordingly, Applicants submit that Pacetti does not remedy the shortcomings of the combination of Ding et al., Choi et al., Mancini et al. Mitoh et al., and Falotico et al. Thus, no *prima facie* case of obviousness has been established, and

Applicants respectfully request the Examiner to reconsider and withdraw the rejection of claim 12 on the basis of this reference.

Compliance of Claim 38 with 35 U.S.C. §103(a)

The Office Action rejects claim 37 as unpatentable over Ding et al. and Choi et al., further in view of Teller et al. (U.S. Patent No. 5,759,376). The Office Action indicates that claim 38 is rejected, but does not appear to provide a substantive rationale for rejecting claim 38. Because the rejection of claim 37 further in view of Teller et al. discusses an electrochemically deposited coating while claim 37 makes no mention of an electrochemically deposited coating, and because claim 38 recites an electrochemically deposited coating and is indicated as being rejected, Applicants presume that the rejection on the basis of Ding et al. and Choi et al. further in view of Teller et al. relates to claim 38, and not to claim 37. Applicants respectfully request reconsideration of this rejection of claim 38 for the reasons set forth below.

For the reasons articulated above with respect to claims 1-5, 7, 8, 13 and 37, Applicants respectfully submit that the combination of Ding et al. and Choi et al. is improper with respect to the claims of this application.

With respect to Teller et al., to Applicants' understanding this reference discloses a method for the electrochemical deposition of hydroxyapatite onto metal and ceramic surfaces. Teller et al. do not disclose the coating of a deformable medical device such as a stent. Further, Teller et al. disclose that the typical layer thickness is in the range of 5-25 μm (Teller et al. at Abstract; column 2 lines 34-37; and Example 6). Thus, not only does Teller et al. fail to remedy the deficiencies noted with respect to the combination of Ding et al. and Choi et al. in respect of coating a deformable substrate with a ceramic, as discussed above, but Teller et al. arguably teach away from using a coating having a thickness of no more than 1 μm as claimed, because a typical layer thickness of 5-25 μm is disclosed, and is characterized as being "an optimum layer thickness" in the Abstract of Teller et al. Accordingly, Applicants respectfully submit that Teller et al. cannot properly be combined with Ding et al. and Choi et al., and no *prima facie* case of obviousness has been established with respect to claim 38. The Examiner is, therefore, respectfully requested to withdraw the rejection of claim 38.

Reconsideration

It is believed that all claims of the present application are now in condition for allowance.

Reconsideration of this application is respectfully requested. If the Examiner believes that a teleconference would expedite prosecution of the present application the Examiner is invited to call the Applicant's undersigned attorney at the Examiner's earliest convenience.

Any amendments or cancellation or submissions with respect to the claims herein is made without prejudice and is not an admission that said canceled or amended or otherwise affected subject matter is not patentable. Applicant reserves the right to pursue canceled or amended subject matter in one or more continuation, divisional or continuation-in-part applications.

Please grant any extensions of time required to enter this response and charge any fees in addition to fees submitted herewith that may be required to enter/allow this response and any accompanying papers to our deposit account 02-1037 and credit any overpayments thereto.

Respectfully submitted,

By: _____

Gerald O.S. Oyen
Registration No. 27,280
tel: 604.669.3432 ext. 8935
fax: 604.681.4081
e-mail: goyen@patentable.com

Vancouver, B.C.
CANADA